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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,438	09/30/2003	Jonathan A. Rowley	P-564SP1	2613
46851	7590	09/20/2006	EXAMINER	
DAVID W. HIGHET BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC110 FRANKLIN LAKES, NJ 07417			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/673,438	ROWLEY ET AL.
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 June 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8,19-25 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-8,19 and 25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 20-24 and 28-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/13/06,  
8/4/05,7/15/05, 6/18/04, 2/23/04, 2/20/04**

**DETAILED ACTION**

A response of 6/13/06 to a restriction requirement of 3/16/06 amended claim 20, added new claims 28-36, canceled Group II claims 9-18 and Group VI claims 26 and 27, and elected Group IV claims 20-24 5 without traverse.

Since added claims 28-36 are dependent on elected claim 20, these claims are included with the elected claims.

Claims 1-8, 19 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, 10 there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/13/06.

Claims examined on the merits are 20-24 and 28-36.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 15 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20 Claims 20-24 and 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 Claim 20 and claims dependent are unclear by not claim 20 being unclear in a) as to material the cells are seeded on when requiring seeding cells on a culture environment. Are the cells seeded on the

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hydrogel scaffold contained by the environment, or are the cells seeded on something else? Furthermore, requiring seeding the cells on a cell culture environment is confusing since an environment is not a physical material on which cells can be seeded. This also applies to 5 b) and c) requiring maintaining cells on a cell culture environment. In c) of the claim, it is unclear as to whether the response results from the test molecule in a) or something else.

Claims 21 and 23 are confusing by requiring seeding to be in an *in vitro* setting and an *in vivo* setting, respectively. It is unclear 10 how "setting" defines "*in vitro*" and "*in vivo*".

Dependent claim 22 is confusing as to how it is further limiting by requiring "said appropriate conditions" to comprise cell culture conditions. The appropriate conditions in claim 20 would have to be cell culture conditions since cell culturing is being carried out when 15 the appropriate conditions are required.

Dependent claim 24 is unclear how it further limits claim 23 by requiring the cell culture environment to be in a subject since it is unclear how an *in vivo* setting can occur in claim 23 and not be in a subject.

20 Dependent claim 30 is unclear by requiring a plurality of cell culture environments distributed on a surface since an environment is not a material object that can be distributed. This also applies to claim 32 requiring attaching a plurality of cell culture environments to a platform.

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Dependent claims 35 and 36 are confusing by requiring identical constituents and different constituents, respectively, since the hydrogel, test molecule and cells in claim 20 are constituents that are not identical. The constituents that are identical and different  
5 is uncertain.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.  
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20

Claims 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Guarino et al (6,967,086 B2).

The claims are drawn to a method of assaying cellular function in response to a test molecule by seeding cells onto a porous hydrogel scaffold containing at least one non-covalently attached test molecule, culturing the cells and determining the cells response.  
25  
30

Guarino et al disclose (col 3, lines 18-23 and 46-67, and col 9, lines 35-45) a system for assay of effects of different materials, bioactive agents and combinations thereof on cells in two or three dimensional culture. The system can also be used for cytotoxicity assays for the effects of drugs, toxins or chemicals on eukaryotic or

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prokaryotic cells. A cell suspension is added to a porous three-dimensional scaffold made of natural or synthetic polymers (col 4, lines 51-54), and containing a non-covalently bound (col 7, line 34) biomimetic molecule that functions as a growth effector molecule (col 5 4, line 49, and col 6, line 12 to col 7, line 39), incubating the cells (col 4, lines 36-43, and paragraph bridging cols 5 and 6), and determining cell response to the biomimetic molecule (Examples 1-5).

The process of Guarino et al assays cellular function in response to a test molecule, and is encompassed by the present claims.

10

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20

25

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

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U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Drohan et al (6,124,273).

5 The claims require the cells to be seeded in an *in vivo* setting.

Drohan et al disclose (col 21, lines 3-6) an *in vivo* assay where a chitin hydrogel containing HBGF-1 $\beta$  is tested for its ability to promote healing *in vivo*.

It would have been obvious to use the scaffold of Guarino et al  
10 containing a biomimetic molecule to determine its effect on healing *in vivo* as suggested by Drohan et al.

***Claim Rejections - 35 USC § 103***

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guarino et al in view of Rowley (document 75 on 1449 of 2/20/04).

15 The claim requires the scaffold to comprise covalently cross-linked alginate.

Rowley discloses using covalently cross-linked alginate for cell culture and tissue engineering.

It would have been obvious to use covalently cross-linked alginate to form the scaffold of Guarino et al as suggested by Rowley disclosing the function of covalently cross-linked alginate for cell culture and tissue engineering, and Guarino et al disclosing using a natural polymer to form the scaffold, and forming the scaffold from a hydrogel forming polymer.

***Claim Rejections - 35 USC § 103***

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guarino et al in view of Prestwich et al (document on 1449 of 2/23/04).

5       The claim requires the scaffold to comprise covalently cross-linked hyaluronic acid.

Prestwich et al disclose using covalently cross-linked hyaluronic acid as a cross-linked hydrogel scaffold for tissue engineering (abstract, page 93).

10       It would have been obvious to use covalently cross-linked hyaluronic acid to form the scaffold of Guarino et al as suggested by Prestwich et al disclosing the function of covalently cross-linked hyaluronic acid to form a cross-linked hydrogel scaffold for tissue engineering, and Guarino et al disclosing using a natural polymer to 15 form the scaffold, and forming the scaffold from a hydrogel forming polymer.

***Claim Rejections - 35 USC § 103***

Claims 30-33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guarino et al in view of Sabatini et al 20 (2003/00332203A1).

The claims a plurality of cell culture environments distributed on a surface of a platform in the form of spots, forming an array of cell culture environments.

Sabatini et al disclose small molecule microarrays for 25 identifying a small molecule by observing the effect of the molecule

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on an observable characteristic of a biological sample or test element such as a cell (abstract and paragraphs 0004-0023). A small molecule-cell array is provided by affixing a small molecule to the surface of a hydrogel at discrete locations (paragraphs 0163 and 0164), and  
5 adding cells to the surface.

It would have been obvious to provide the biomimetic molecule on the scaffold of Guarino et al to form a small molecule-cell array to obtain the function of the array as taught by Sabatini et al.

Parent application 10/259,817 cannot antedate Sabatini et al  
10 since the parent application fails to have an adequate written description of the presently claimed invention.

***Claim Rejections - 35 USC § 103***

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 30-33, 35 and 36 above, and  
15 further in view of Prestwich et al.

When carrying out the assay of Guarino et al with a small molecule-cell array as suggested by Sabatini et al as set forth above, it would have been obvious to us hyaluronic acid to form the hydrogel as suggested by Prestwich et al using a hydrogel formed from  
20 hyaluronci acid for tissue engineering.

***Claim Rejections - 35 USC § 102***

Claims 20-22 and 28-36 are provisionally rejected under 35 U.S.C.  
102(e) as being anticipated by copending Application No. 10/260,737  
which has a common inventor with the instant application. Based upon  
25 the earlier effective U.S. filing date of the copending application,

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it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

5       The application discloses a method for assaying cellular function in response to a test molecule as presently claimed. Parent application 10/259,817 cannot antedate 10/260,737 since the parent application fails to have an adequate written description of the presently claimed invention.

10       This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This 15 rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

***Claim Rejections - 35 USC § 103***

Claims 23 and 24 are provisionally rejected over the copending Application as applied above, and in further view of Drohan et al for 20 the type of reasons set forth above when rejecting the claims.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the 25 conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-22 and 28-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-10, 12, 13, 17 and 44-83 of copending Application No. 10/260,737. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed method of assaying cellular response to a test molecule would have been obvious from the device and method of the copending application claims for assessing effects of a scaffold on cell growth.

This is a provisional obviousness-type double patenting rejection

because the conflicting claims have not in fact been patented.

#### ***Double Patenting***

Claims 23 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over the copending application claims as set forth above, and in further view of Drohan

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et al for the type of reasons set forth above when rejecting the claims.

***Double Patenting***

Claims 20-22 and 28-36 are provisionally rejected on the ground  
5 of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 8-12, 16, 17, 19, 31, 32, 34-36, 38 and 46-65 of copending Application No. 10/259,817 in view of Guarino et al and Sabatini et al.

It would have been obvious to use the composition, array and kit  
10 of the copending application claims in an assay of cellular response to a test compound contained by a hydrogel scaffold as suggested by Guarino et al and Sabatini et al.

This is a provisional obviousness-type double patenting rejection.

15

***Double Patenting***

Claims 23 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of the copending Application as applied above, and in further view of Drohan et al for the type of reasons set forth above  
20 when rejecting the claims.

***Conclusion***

Jaffe (6,632,622 B2) is made of record to further show assaying cellular response.

Chaney et al (7,074,615 B2) is made of record to further show a  
25 scaffold for culturing cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be  
10 obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [http://pair-  
15 direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

20 DMN  
9/16/06